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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/398,399	09/17/1999	GLEND A. DELENSTARR	10981620-1	1056

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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 07/29/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/398,399

Applicant(s)

DELENSTARR ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-68 71-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-68 and 71-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1634.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 19 June 2002 has been entered.

Claim Objections

3. Claims 51, 52, and 55 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 50 requires that the labeled target be contacted with the array of probes. Consequently, claim 51 does not add any limitation to claim 50 that is not already there. Claim 52, however, effectively broadens claim 50, as the previously

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labeled target is no longer labeled. Claim 55 requires the probe to be in an array yet claim 50 already recites that the probe is in an array.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 50-59, 71, 74-80, and 83-84 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

6. The method of claim 50 does not require the separation/wash/removal of unbound label, be it on the target at time of hybridization or added subsequent to hybridization. Accordingly, the method as claimed fairly encompasses a hybridization step whereby one would not be able to detect the hybridization product. Claims 51-57, which depend from said claim 50, do not overcome this issue and are similarly rejected.

7. Claim 58 is not enabled, as it requires detection yet no label is required nor is any detectable means are recited. It is further noted that one not be required to differentiate between the placement of the probe and background features. Accordingly, the specification has not enabled a method whereby one is to detect that which is undetectable and where it location on a substrate, even if detectable, is not known or characterized as being in some positional relationship to the background feature.

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8. Claims 59, 71, and 74-80, like that of claim 58, *supra*, require detection where no detectable means are required/recited. Further, the method does not require any separation of unbound label, if used, from the assay.

9. Claim 64-67, while requiring a step whereby one is to separate "non-hybridized target nucleic acids from said array," does not require that unbound label be also removed. Without being able to discriminate where label is bound or not bound, one would not be able to determine what constitutes background or actual signal emanating from a labeled duplex structure. Claims 83 and 84, which depend from said claim 67, fail to overcome this issue and are similarly rejected.

10. It is noted that while the specification recites alternative methodologies whereby label and separation and detection steps are recited, such limitations, though found in the body of the disclosure, are not read into the claims, but rather, the claims are read as broadly as is reasonably possible.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 50-57 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claims 50 and 60 recite the limitation "said fluorescently labeled fully complementary target" in step (a). There is insufficient antecedent basis for this limitation in the claim. Claims 51-57, which depend from claim 50, fail to overcome this issue and are similarly rejected.

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14. Claims 50-59, 71, 74-80, and 83-84 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The combined removal of unhybridized target sequences, labeled or unlabeled, as well as the removal of unbound label wherein these steps take place prior to any detection step.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 50-68 and 71-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dehlinger (US Patent 5,723,320) in view of Fodor et al. (US Patent 5,445,934), Blanchard et al. (*Biosensors and Bioelectronics*, Vol. 11, No. 6/7, 687-690, 1996), and Brink et al. (US Patent 5,563,034).

19. Dehlinger, column 13, discloses methods of using arrays of oligonucleotides. Such methods encompass sequencing -by-hybridization, diagnostics, and gene expression. Column 12 specifically teaches that an array may contain internal control sequences. Column 12 describes an assortment of probes that can range in lengths from 10 to 50 bases in length.

20. Dehlinger does not teach use of applicant's "background nucleic acid feature" nor the use of sequences represented by SEQ ID NOS: 05 to 32.

21. Fodor et al., column 15, discloses the synthesis of arrays of oligonucleotides that comprise up to 10^8 different sequences which, at column 25, are further defined as optionally being oligonucleotides and that these oligonucleotides can be dodecanucleotides or larger. The examiner takes notice that an array of 10^8 oligonucleotides would accommodate all possible oligonucleotides 13 bases in length (6.71×10^7 oligonucleotides). Accordingly, an oligonucleotide array comprising all possible 13-mers would, by default, comprise those sequences explicitly recited by applicant that are 13 bases or less in length.

22. Blanchard et al., teach explicitly of the production of oligonucleotide arrays that comprise all possible oligonucleotides of a given length.

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23. Neither Fodor et al., nor Blanchard et al., teach the use of sequences that will not hybridize to their complement.

24. Brink et al., columns 3-4, disclose and encourage the use of control sequences. As set forth at column 3:

The problem [of background signal or noise] can be resolved by the use of Type I and Type II negative control probes described herein. These probes are analogous in almost every respect to the experimental probes, except in their ability to bind the intended nucleic acid target. In addition, if there is non-specific probe binding, probe trapping, or insufficient washing, the experimental and negative control probe will allow one to accurately determine how much of the experimental signal is due to binding of the experimental probe to the target nucleic acid.

25. It would have been obvious to one of ordinary skill in the art at the time that the invention was made to have incorporated "negative control probes" (applicant's "background nucleic acid feature") into an array and method of Dehlinger wherein said array had virtually every oligo of a given length (Fodor et al. and Blanchard et al.) and to have done so with the enhanced accuracy afforded by the use of control sequences (Brink et al.). In view of the motivation provided by Brink et al., and the well-developed state of the art, the ordinary artisan would not only have been highly motivated but would have also had a most reasonable expectation of success.

26. For the above reasons, and in the absence of convincing evidence to the contrary, the method of claims 50-67 and 71-84, as well as the kit of claim 68 are rendered obvious by the prior art of record.

Conclusion

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

28. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

29. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
July 24, 2002